



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,152	09/25/2006	Xin-Yun Huang	2003080-0205 (SK-1071-US2)	4442
63411 7590 07/21/2009 CHOATE, HALL & STEWART LLP SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH TWO INTERNATIONAL PLACE BOSTON, MA 02110			EXAMINER HAVLIN, ROBERT H	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 07/21/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,152	Applicant(s) HUANG ET AL.	
	Examiner ROBERT HAVLIN	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 and 45-47 is/are pending in the application.
- 4a) Of the above claim(s) 13, 15, 21-26, 28, 29 and 31-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 and 45-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

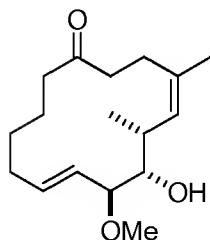
Status of the claims: Claims 1-42 and 45-47 are currently pending.

Priority: This application is a 371 of PCT/US04/09380 (03/26/2004) which claims benefit of 60/458,827 (03/28/2003) and claims benefit of 60/496,165 (08/19/2003).

RCE: A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/13/09 has been entered.

Election/Restrictions

1. Applicant previously elected the following species (stated to read on claims 1-12, 14, 16-20, 27, 30, 41-62):



Because the generic claim 1 was found unpatentable, in accordance with the requirement for restriction and election of species practice, the claims are hereby restricted to the elected species only. Claims 13, 15, 21-26, 28, 29, 31-40 are withdrawn because they do not read on the elected species.

RESPONSE TO APPLICANT REMARKS

Applicant argues that the prior final rejection was improper. The examiner disagrees and maintains that the finality was proper as explained in the advisory action of 4/17/09.

Claim Rejections - 35 USC § 112

2. Claims 48-62 were rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating breast tumor metastasis in a subject. Applicant has cancelled the claims, therefore the rejection is **withdrawn**.

3. Claims 43 and 44 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has cancelled the claims, therefore the rejection is **withdrawn**.

Claim Rejections - 35 USC § 102

4. Claims 1, 11, 16, and 27 were rejected under 35 U.S.C. 102(b) as being anticipated by GB 1036084. Applicant amended the claims to delete the "R4" alternative of hydrogen. Thus the claims no longer read on the prior art reference and the rejection is **withdrawn**.

NEW CLAIM REJECTIONS

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

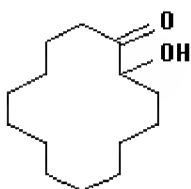
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1626

2. Claims 1-11, 16, and 27 rejected under 35 U.S.C. 102(b) as being anticipated by Singh et al. (Indian Journal of Chemistry, Section B: Organic Chemistry Including Medicinal Chemistry (2002), 41B(2), 423-426).

Singh et al. teaches the following compound in water, ethanol and xylene which is within the scope of the instant claims.



The broadest reasonable interpretation of the claims in view of the following definitions in the specification make it clear that the prior art reads on the claims.

3) Pharmaceutical Compositions

[0387] In another aspect of the present invention, pharmaceutical compositions are provided, which comprise any one of the compounds described herein (or a prodrug, pharmaceutically acceptable salt or other pharmaceutically acceptable derivative thereof), and optionally comprise a pharmaceutically acceptable carrier, adjuvant or vehicle. In certain other embodiments, the compositions of the invention are useful for the treatment of cancer and disorders associated with metastasis and/or angiogenesis. In certain embodiments, the inventive compositions optionally further comprise one or more additional therapeutic agents. In certain other embodiments, the additional therapeutic agent is a cytotoxic agent, as discussed in more detail herein. In certain other embodiments, the additional therapeutic agent is an anticancer agent. In certain embodiments, the anticancer agent is an epothilone, taxol, radicicol or TMC-95A/B. In certain embodiments, the epothilone is 12,13-desoxyepothilone B, (E)-9,10-dehydro-12,13-desoxyEpoB and 26-CF3-(E)-9,10-dehydro-12,13-desoxyEpoB. Alternatively, a compound of this invention may be administered to a patient in need thereof in combination with the administration of one or more other therapeutic agents. For example, additional therapeutic agents for conjoint administration or inclusion in a pharmaceutical composition with a compound of this invention may be an antiangiogenesis agent or anticancer agent approved for the treatment of cancer, as discussed in more detail herein, or it may be any one of a number of agents undergoing approval in the Food and Drug Administration that ultimately obtain approval for the treatment of cancer.

[0388] As described above, the pharmaceutical compositions of the present invention additionally comprise a pharmaceutically acceptable carrier, adjuvant or vehicle, which, as used herein, includes any and all solvents, diluents, or other liquid vehicle, dispersion or suspension aids, surface active agents, isotonic agents, thickening or emulsifying agents, preservatives, solid binders, lubricants and the like, as suited to the particular dosage form desired.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1626

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-42 and 45-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims use the following language:

whereby the composition is formulated for administration to a subject at a dosage between about 0.1 mg/kg to about 50 mg/kg of body weight,

without making clear which component of the composition is relative to body weight.

For example, is it the total mass of the composition or only the mass of the active ingredient that is relative to the body weight.

5. Claims 1-42 and 45-47 are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention due to use of "a therapeutically effective amount" without any reference to a therapy. One of ordinary skill in the art would not know what this amount is because a therapy has not been defined and it is not clear which therapies applicants are referring to. Therefore one of skill in the art would not be apprised of the metes and bounds of the claims.

Conclusion

The claims are not in condition for allowance.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is

Art Unit: 1626

(571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/
Examiner, Art Unit 1626